K093619
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Attachment D - 510(k) Summary

JUN 17 2010

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Contact Persons:	Jacinta Kilmartin, Regulatory Affairs Specialist Sinead Burke Senior Regulatory Affairs Specialist
Phone: Fax: Date:	+353 61 334440 +353 61 239293 November 20, 2009
Trade Name:	Evolution™ Esophageal Stent System - Fully Covered
Common Name:	Esophageal Stent
Classification Name:	Esophageal Prosthesis (21 CFR 878.3610, Product Code: ESW)
Legally Marketed Devices:	Evolution™ Esophageal Stent System
Description of the Device:	Stent Description: This flexible, self-expanding stent is constructed of nitinol wire with a silicone cover. The total length of the stent is indicated by radiopaque markers on the inner catheter, indicating the actual length of the stent at nominal stent diameter. There are lasso loops at both the proximal and distal ends of the

	stent whose purpose is to reposition the stent as needed. Introducer System Description: The stent is mounted on an inner catheter, which accepts a 0.035 inch wire guide and is constrained by an outer catheter. A pistol-grip delivery handle allows stent deployment or recapture.
Indications for use:	This device is used to maintain patency of malignant esophageal strictures and / or to seal tracheoesophageal fistulas.
Comparison of Characteristics:	The proposed device is substantially equivalent to the currently marketed device, the Evolution™ Esophageal Stent System, as cleared by K080359.
Performance Data:	The risks associated with the modifications to our subject device have been adequately addressed through our Design Control Process. Recommendations as per the FDA guidance document *Guidance for Industry – Guidance for the content of Premarket Notifications for Esophageal and Tracheal Prostheses (28-April-1998)* with respect to biocompatibility, sterility, labelling and performance testing including deployment testing, dimensional testing, expansion force testing, compression force testing, corrosion testing and tensile strength testing have been applied to the proposed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G6
Silver Spring, MD 20993-0002

Ms. Jacinta Kilmartin
Regulatory Affairs Specialist
Cook Ireland Ltd.
National Technology Park
Limerick
IRELAND

JUN 17 2010

Re: K093619
Trade/Device Name: Evolution™ Esophageal Stent System – Fully Covered
Regulation Number: 21 CFR §878.3610
Regulation Name: Esophageal prosthesis
Regulatory Class: II
Product Code: ESW
Dated: June 10, 2010
Received: June 14, 2010

Dear Ms. Kilmartin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093619

Device Name: Evolution™ Esophageal Stent System - Fully Covered

Indications for Use:

This device is used to maintain patency of malignant esophageal strictures and / or to seal tracheoesophageal fistulas.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093619